

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF OREGON
EUGENE DIVISION

DOROTHY M. MAYFIELD
PLAINTIFF

V.

MERCK & CO., INC.
a New Jersey corporation
DEFENDANT

JURY TRIAL DEMANDED

Civil Action No. _____

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff DOROTHY M. MAYFIELD by and through his undersigned attorneys
sue Defendant Merck & Company, Inc., and allege as follows:

I. JURISDICTION AND VENUE

1. This Court has jurisdiction pursuant to 29 U.S.C. §§ 1332, as complete diversity exists between Plaintiff and Defendant. Plaintiff is a resident of the State of Oregon, and Defendant is incorporated and has its primary place of business in the State of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds \$75,000.
2. Venue is proper within this district and division pursuant to 28 U.S.C. §1391, as a substantial number of events, actions, or omissions giving rise to the Plaintiff's claims occurred in this district. At all times relevant to this matter, Defendant Merck conducted substantial business in this district.

II. PARTIES

3. At all relevant times, Plaintiff was a resident of Oregon. Plaintiff used FOSAMAX from approximately 2003 until she was diagnosed with osteonecrosis of the jaw in 2007.
4. Defendant is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's principal office is located at One Merck Drive, Whitehouse Station, New Jersey 08889.
5. Defendant was at all relevant times authorized to conduct business in the State of Oregon.
6. Defendant has regularly transacted business in the State of Oregon and continues to do so.
7. At all relevant times Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Paget's Disease.
8. Defendant either directly or through its agents, apparent agents, servants or employees at all relevant times, sold and distributed FOSAMAX in the State of Oregon.
9. Defendant derives substantial revenue from pharmaceutical products used or consumed in the State of Oregon.
10. Defendant expected, or should have expected, that its business activities could or would have consequences within the State of Oregon.

11. Defendant placed FOSAMAX into the stream of worldwide commerce and interstate commerce in the United States. It did so without adequate testing and with now warning that the drug carried with it a risk of causing osteonecrosis of the jaw.

III. SUMMARY OF THE CASE

12. Defendant, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other uses.
13. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff have suffered and may continue to suffer severe and permanent personal injuries, including osteonecrosis of the jaw.
14. Defendant concealed and continues to conceal its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff, other customers, and the medical community.
15. Defendant failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.
16. As a result of Defendant's actions and inaction, Plaintiff was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause Plaintiffs' various injuries and damages. Plaintiff accordingly seeks compensatory damages.

IV. FACTUAL BACKGROUND

17. At all relevant times Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.
18. In September 1995, the United States Food & Drug Administration ("FDA") approved Merck's compound alendronate for various uses, including the treatment of osteoporosis and Paget's Disease. Alendronate is marketed by Defendant Merck as FOSAMAX.
19. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's Disease. Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.
20. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate contains a nitrogen atom. The Physicians Desk Reference ("PDR") for FOSAMAX confirms that the molecule contains a nitrogen atom.
21. Throughout the 1990's and 2000's, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the

upper gastrointestinal tract, Merck knew or should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse event profiles to other drugs with in this specific subclass of bisphosphonates (i.e., those containing nitrogen).

22. Merck knew or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck know or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.
23. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).
24. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.
25. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and typically is not reversible.
26. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and

verifying the safety of FOSAMAX with respect to Osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

27. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.
28. Since FOSAMAX was released, the FDA has received a significant number of reports of osteonecrosis of the jaw among users of FOSAMAX.
29. On August 25, 2004, the United States Food & Drug Administration ("FDA") posted its ODS Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.
30. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, FOSAMAX.
31. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Defendant to specifically warn about the risk of osteonecrosis of the jaw. Defendant has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.

32. Rather than warn patients, and despite knowledge known by Defendant about increased risk of osteonecrosis of the jaw on patients using FOSAMAX, Defendant continues to defend FOSAMAX, mislead physicians and the public, and minimize unfavorable findings.
33. FOSAMAX is one of Defendant's top selling drugs, averaging more than \$3 billion a year in sales.
34. Consumers, including Plaintiff, who have used FOSAMAX for treatment of osteoporosis, have several alternative safer products available to treat the condition.
35. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff, or the medical community, of such risks.
36. As a direct result, Plaintiff was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff requires and will in the future require ongoing medical care and treatment.
37. Plaintiff has suffered from mental anguish from the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.
38. Plaintiff was prescribed and began taking FOSAMAX in 2003.
39. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.
40. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe osteonecrosis of the jaw.

41. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.
42. Plaintiff used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.
43. Plaintiff would not have used FOSAMAX had the Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.
44. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.
45. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions and misrepresentations.

COUNTS

COUNT I: NEGLIGENCE

46. Plaintiff restates the allegations set forth above as if fully rewritten herein.

47. Defendant owed Plaintiff and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

48. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

a.

failing to properly and thoroughly test FOSAMAX before releasing the drug to market;

b.

failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX;

c.

failing to conduct sufficient post-market testing and surveillance of FOSAMAX;

d.

designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e.

failing to exercise due care when advertising and promoting FOSMAX; and

f.

negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant know or should have known of its adverse effects.

49. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses of damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.
50. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT II: STRICT LIABILITY

51. Plaintiff restates the allegations set forth above as if fully rewritten herein.
52. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff.
53. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach

consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

54. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.
55. FOSAMAX failed to perform safely when used by ordinary customers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.
56. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.
57. FOSAMAX was defective in design of formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.
58. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.
59. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

60. Plaintiff could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.
61. As a direct and proximate consequence of Defendant's conduct, Plaintiff sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.
62. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT III: BREACH OF EXPRESS WARRANTY

63. Plaintiff restates the allegations set forth above as if fully rewritten herein.
64. Defendant expressly represented to Plaintiff and other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

65. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.
66. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.
67. Plaintiff, other consumers, and the medical community relied upon Defendant's express warranties.
68. As a direct and proximate result of Defendant's actions, Plaintiff sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.
69. Defendant's conduct as described above was committed with knowledge, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff

to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT IV: BREACH OF IMPLIED WARRANTY

70. Plaintiff restates the allegations set forth above as if fully rewritten herein.
71. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.
72. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.
73. Defendant was aware that consumers, including Plaintiff would use FOSAMAX for treatment of osteoporosis and for other purposes.
74. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.
75. Defendant breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.
76. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.
77. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.
78. As a direct and proximate result of Defendant's action, Plaintiff sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to

suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

79. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT V: FRAUDULENT MISREPRESENTATION

80. Plaintiff restates the allegations set forth above as if fully rewritten herein.
81. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a.

Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b.

Defendant represented FOSAMAX was safer than other alternative medications.

82. Defendant know that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.
83. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.
84. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.
85. Plaintiff's doctors and others relied upon the representations.
86. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.
87. As a direct and proximate result, Plaintiff sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

88. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT VI: FRAUDULENT CONCEALMENT

89. Plaintiff restates the allegations set forth above as if fully rewritten herein.
90. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:

a.

Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

b.

Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.

91. Defendant had sole access to material facts concerning the dangers and unreasonable risks of FOSAMAX.
92. The concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.

93. The concealment of information and the misrepresentations about FOSAMAX were made by the Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.
94. Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's doctors and Plaintiff.
95. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentations, Plaintiff suffered osteonecrosis of the jaw and was cause to suffer severe and permanent injuries, including pain and mental and physical anguish and suffering, including a diminished capacity for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of the injury. Plaintiff has suffered and will continue to suffer a loss of wages and wage-earning capacity and has incurred expense for medical care and treatment due to the injuries caused by FOSAMAX.
96. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT VII: EQUITABLE RELIEF
MEDICAL MONITORING PROGRAM AND PROPER LABELING

97. Plaintiff restates the allegations set forth above as if fully rewritten herein.
98. As a direct and proximate result of Defendant's acts, Plaintiff faces an increased susceptibility to injuries as described herein. This irreparable threat to her health

can only be mitigated by the creation of a medical monitoring fund to provide for a medical monitoring program, including: notifying Plaintiff of the defects and the potential medical harm; funding a program for the surgical treatment of osteonecrosis of the jaw; funding a study of the long term effects of FOSAMAX within the body of Plaintiff; gathering and forwarding to treating physicians information relating to the diagnosis and treatment of injuries which may result from the product; aiding in the early diagnosis and treatment of resulting injuries; and providing funding for diagnosis and preventable medical treatment, particularly dental and oral monitoring.

99. Plaintiff has no adequate remedy in law in that monetary damages alone do not compensate for the insidious and continuing nature of the harm to her, and only a medical monitoring program which notified the Plaintiff and aids in correcting the problems can prevent the greater harms which may not occur immediately and which may be preventable, if proper research is conducted and the health risks are diagnosed and treated before they occur or become worse.
100. Plaintiff has suffered irreparable harm as alleged herein and, in the absence of equitable relief, Plaintiff will suffer further irreparable harm such as death and severe and debilitating injuries from continued retention of the defective drug. Without a medical monitoring program, Plaintiff might not receive prompt medical care which could prolong her productive life, increase prospects for improvement and minimize disability.
101. Additionally, Defendant has refused to abide by the FDA's request to amend its product labeling information to warn physicians and patients about the risk of

osteonecrosis of the jaw. Because of this failure, prescribing physicians are unable to warn patients to be aware of precursors symptoms which, if properly observed and reported to the physician, could result in discontinuation of FOSAMAX therapy and the prevention or mitigation of osteonecrosis of the jaw.

102. This Court should use its equitable powers, in the interest of public safety and in order to make sure that prescribing physicians have a complete understanding of the risks associated with FOSAMAX, to require Defendant to change its label in a format approvable to the FDA to adequately warn physicians and FOSAMAX patients about the risk of osteonecrosis of the jaw and steps which can be taken to prevent or mitigate its occurrence.

COUNT VIII: PUNITIVE DAMAGES

103. Plaintiff restates the allegations set forth above as if fully rewritten herein.
104. Defendant has repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations as which warnings relating to public hazards should be warned about.
105. For instance, in March 2000, Defendant completed a study called VIGOR (VIOXX Gastrointestinal Outcomes Research) relating to its prescription cox-2 inhibitor, VIOXX, the VIGOR study showed that VIOXX patients had more than double the rate of serious cardiovascular problems that those on Naproxen, and older non-steroidal anti-inflammatory drug. The study was published in the New England Journal of Medicine.
106. In September 2001, the FDA warned Defendant to stop misleading doctors about VIOXX's effect on the cardiovascular system. Defendant Merck was admonished

to stop minimizing the risks of the drug in its marketing. Despite that, Defendant refused to adequately warn physicians and patients about the risk of heart attacks and VIOXX.

107. On August 25, 2004, a representative from the FDA presented results of a database analysis of 1.4 million patients. The analysis demonstrated that VIOXX users were more likely to suffer a heart attack or sudden cardiac death than those taking Celebrex or older non-steroidal drugs. The FDA representative concluded that VIOXX was linked to more than 27,000 heart attacks or sudden cardiac deaths nationwide from the time it came on the market in 1999 through 2003.
108. On August 26, 2004, Defendant released a press statement which refuted the FDA analysis and restated Defendant's support for the cardiovascular safety of VIOXX.
109. On September 30, 2004, Defendant recalled VIOXX from the market, after having to halt the APPROVe study (Adenomatous Polyp Prevention on Vioxx). The study was underway to evaluate the use of VIOXX for recurrent colon polyps. The researchers found an alarming number of cardiovascular events among the drug's users in the APPROVe study.
110. At that same time, Defendant was aware that the FDA, as of August 24, 2004, was advising Defendant to warn about the risk of osteonecrosis of the jaw for its FOXAMAX patients. Because Defendant knew that its blockbuster drug VIOXX was about to be pulled from the market, placing more importance on the \$3 billion+ annual sales of FOSAMAX, Defendant deliberately chose to not amend its packaging of FOSAMAX to include the risk of osteonecrosis of the jaw,

fearing that such a warning would result in a reduced revenues for its second largest income producer, FOSAMAX.

111. Defendants' acts were willful and malicious in that Defendant's conduct was carried out with a conscious disregard for the safety and right of Plaintiff. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendant in an amount appropriate to punish Defendant, and deter similar conduct in the future.

WHEREFORE, Plaintiff prays for judgment against Defendant, jointly and severally as follows:

1. For general damages in an amount to be proven at the time of trial;
2. For special damages in an amount to be proven at the time of trial;
3. For exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendant or to deter Defendant and others from repeating the injurious conduct alleged herein;
4. For pre-judgment and post-judgment interest on the above general and special damages;
5. For costs of this suit and attorneys' fees; and
6. All other relief that Plaintiff may be entitled to at equity or at law.

V: DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

DATED this 15th day of May 2007

Respectfully submitted,

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